## PATENT COOPERATION TREATY

From the

INTERNATIONAL PRELIMINARY EXAMINING

To:

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## **PCT**

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Rule 71.1)

IMPORTANT NOTIFICATION

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Applicant

Bio-MED Photonics Co., Ltd. et al

- 1. The applicant is hereby notified that this International Preliminary Examining Authority transmits here with the international preliminary report on patentability and its annexes, if any, established on the international application.
- 2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
- 3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

#### 4. REMINDER

The applicant must enter the national phase before each elected office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Atricle 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed invention is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

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As shown in the above table, when the mouse IgG reference material was immobilized in front of the test line, the lowest CV value for AFP concentration was found. Therefore, this case provides excellent reproducibility in AFP concentration.

### Example 16

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# Dispensation of Ag line with which Ag or detector reacts in back of the viewing window

The hook effect occurs when Ag is present in excessive amounts, and brings about false negative results that cause fatal wrong diagnosis. A method of quantifying Ag by inducing binding of a capture antibody to a detector and Ag in a mixture like the present system has a potential of causing the hook effect and thus errors in quantitative assay. In a normal case, when an excessive detector binds to both free Ag and Ag immobilized in an Ag line, signals are generated. As shown in Figs. 18 and 20, signals increase according to the increased concentration of Ag in the test line 30, whereas, in the Ag line 61, signals decrease according to the

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